PRINT FORM

MOREHOUSE SCHOOL OF MEDICINE

Institutional Biosafety Committee

Biosafety Laboratory Protocol Submittal Form

Office use only:
BSL Number _____
Date received _____
Date reviewed _____
Review panel _____
Reviewers' recommendation _____
Approval date _____

All research conducted at this institution must conform to all applicable guidelines, regulations and directives as established through the various authorities. The 5th edition of the Biosafety in Microbiological and Biomedical Laboratories is one good reference, BMBL - CDC/NIH publications (https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2020-P.pdf)

This form will provide documentation that all applicable research concerns have been properly determined and addressed or this submission will be returned for additional clarification and review.

Provide all references and supplemental documentation required for pertinent for assessment of safety concerns.

Include your "Experimental Design" section of your proposal with this application.

Submission date: _____

Application type:

☐ Initial protocol

☐ Renewal
- ☐ Changes
- ☐ No changes

☐ Amendment
Protocol Number _____

Category the proposed research will involve:

☐ 1. Research involving animal or human subjects IACUC Protocol # _____ IRB Protocol # _____

☐ 2. Other research not involving IACUC or IRB approval

General information - all submissions

Principal Investigator: _____ Project Supervisor: _____
(If different from Principal Investigator)

Project Title: _____

Describe in **NON-TECHNICAL LANGUAGE** the objectives of the protocol for research. If amending a previously submitted and approved protocol, describe the changes and complete all the applicable sections.

INSTRUCTIONS: All forms provided must be returned fully completed for the Institutional Biosafety Committee review. If received within two weeks prior to the beginning of the month, they will normally be reviewed in the next Institutional Biosafety Committee meeting. Failure to complete all required fields may result in the forms being returned and delays for the review process.

- **Submit an electronic copy to cbynum@msm.edu.**

For all questions, please contact: Charles Bynum: cbynum@msm.edu (404) 756-5783 or Dr. Shailesh Singh: shsingh@msm.edu (404) 756-5718.

Biosafety Information:

B1. Describe all procedures and techniques used in this protocol or provide the "experimental design" section from your proposal. If using standardized techniques, please list.

B2. Identify and address all potential hazards, both biological, chemical, and/or physical, associated with this protocol to the personnel, laboratory, animal facility and environment.

Building	Room #	Biosafety Level	Agent/Organisms (CAS #, genus and species)	Shared room	Dual use organisms	Storage area and type of storage (freezer, liquid, etc)

B3. Describe the equipment and procedures used to safely conduct this work.

Primary containment:

☐ Biosafety cabinet

Type:

Class:

Certification date:

☐ Fume hood

Type:

Class:

Certification date:

☐ Source capture unit

Type:

Class:

Certification date:

BSL level:

https://www.cdc.gov/cpr/infographics/biosafety.htm

Describe the universal or standard precautions you will be using for these studies.

http://www.cdc.gov/niosh/

https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines-H.pdf

B4. Do you intend to transport biological or chemical research material(s)?

Transport within MSM campus? ☐ yes ☐ no

Transport outside of the MSM campus? ☐ yes ☐ no

Transport internationally? ☐ yes ☐ no

Describe the equipment and procedures used to ensure the material is transported safely and in accordance with all USDA and DOT requirement.

B5. Have all personnel had the MSM safety training as required? If, no, state why.

Has any additional training been provided?

The following list of personnel will have physical contact potential with agents/organisms and or animals used within this protocol. These include, but are not limited to biological materials, biohazardous agents, recombinant DNA molecules, chemicals which are identifiable with known or presumed risks, radiological materials and equipment which may present safety concerns (cyrogens, lasers,etc).

Approval of the proposed experiments, research protocols is only provided for the personnel identified and listed below. The Biosafety Officer, Chemical Safety Officer, the Institutional Safety Officer and the Biosafety Chairperson must be notified when personnel are **added** or **removed** from this protocol.

Signature from each listed personnel is required and shall indicate that they have been fully informed of any and all potential hazards, safe work practices, availability of medical surveillance and that they will follow all approved laboratory practices and procedures.

Name	Title/Position	Signature	Date of MSM standard training	Bloodborne pathogens	Other training

Animal Research:

C1. Specify animal species to be used in your research: ☐ mice ☐ rats ☐ rabbits ☐ other

specify:

C2. Will genetically altered animals be used? ☐ yes ☐ no

If yes, describe the alterations:

C3. Will you expose these animals to live organisms, including viral vectors? ☐ yes ☐ no

If yes, what organisms or vectors?

C4. Will you expose these animals to a carcinogen? List: http://www.cdc.gov/niosh/topics/cancer/npotocca.html ☐ yes ☐ no

If yes, what carcinogen(s)?

C5. Is it possible that the research material introduced into the animals (recombinant molecules, vectors, toxins, pathogens or carcinogens) could remain a viable hazard in the animal secretions, excrement, tissues and/or soiled bedding? ☐ yes ☐ no

If yes, describe the procedures used to minimize occupational exposures.

C6. Will animals be exposed to cultured cells, tumors or any other biological tissues? ☐ yes ☐ no

If yes, have the cells or tissue been screened or certified to be pathogen free? Which pathogens were screened?

Pathogens, toxins or chemicals:

D1. Are any select agents, P-list chemicals or carcinogens used in your research?

(See lists for select agents at: https://www.epa.gov/hw/defining-hazardous-waste-listed-characteristic-and-mixed-radiological-wastes#PandUand **carcinogens** at: https://www.cdc.gov/niosh/topics/cancer/npotocca.html

If yes, contact the Safety Officer.

D2. Name of pathogens, toxins or hazardous chemicals used in your research.

List agents:

D3. For each biological organism used, complete the following:

Organism # 1. Name, genus and species

Is antimicrobial resistance expressed? ☐ yes ☐ no

If yes, provide details:

Is the organism inactivated before use? ☐ yes ☐ no

If yes, specify the method: ☐ heat ☐ chemical ☐ radiation

Describe how you verify inactivation:

Do you culture the organism(s)? ☐ yes ☐ no

If yes, specify the method:

Do you concentrate the organism(s)? ☐ yes ☐ no

If yes, specify the method: ☐ centifugation ☐ precipitation ☐ filtration ☐ other

specify "other":

Organism # 2. Name, genus and species

Is antimicrobial resistance expressed? ☐ yes ☐ no

If yes, provide details:

Is the organism inactivated before use? ☐ yes ☐ no

If yes, specify the method: ☐ heat ☐ chemical ☐ radiation

Describe how you verify inactivation:

Do you culture the organism(s)? ☐ yes ☐ no

If yes, specify the method:

Do you concentrate the organism(s)? ☐ yes ☐ no

If yes, specify the method: ☐ centifugation ☐ precipitation ☐ filtration ☐ other

specify "other":

Organism # 3. Name, genus and species

Is antimicrobial resistance expressed? ☐ yes ☐ no

If yes, provide details:

Is the organism inactivated before use? ☐ yes ☐ no

If yes, specify the method: ☐ heat ☐ chemical ☐ radiation

Describe how you verify inactivation:

Do you culture the organism(s)? ☐ yes ☐ no

If yes, specify the method:

Do you concentrate the organism(s)? ☐ yes ☐ no

If yes, specify the method: ☐ centifugation ☐ precipitation ☐ filtration ☐ other

specify "other":

D3. Is a toxin used or produced in this research? ☐ yes ☐ no https://www.selectagents.gov/sat/list.htm

Name of toxin(s)

How will the toxin be aliqotted and stored?

Does the toxin have a LD50 more than 180 ng per kg body weight? ☐ yes ☐ no

Largest volume used? Usual volume used?

D4. Are there any P-list or carcinogens used in your research? ☐ yes ☐ no

P List chemicals: https://www.epa.gov/hw/defining-hazardous-waste-listed-characteristic-and-mixed-radiological-wastes#PandU.
Carcinogens: https://www.cdc.gov/niosh/topics/cancer/npotocca.html

List hazardous chemicals:

List quantity:

List carcinogen(s)

List quantity:

Recombinant DNA work:

E1. Is your project EXEMPT according to NIH guidelines? ☐ yes ☐ no https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm

If yes, indicate applicable sections of the Guidelines with a brief description of the protocol. If no, continue below.

E2. List the gene sequence(s) used to make the recombinants. If obtained commercially, list the company and description.

Explain the function(s) of the foreign genetic material used in these experiments:

Are you expressing foreign proteins? ☐ yes ☐ no

If yes, what protein(s) and are there any hazards associated with the expression of these proteins?

E3. List the organisms used as the host or vector. Identify all that apply - prokaryotes, eukaryotes or animals.

Will animals or plants be exposed to the recombinants? ☐ yes ☐ no

If yes, list the plants, cells or animals that will be used:

Will infectious virus, oncogenic agents or toxins be produced by this work? ☐ yes ☐ no

Will animals or plants be exposed to the recombinants? ☐ yes ☐ no

If yes, list the plants, cells or animals that will be used:

Will infectious virus, oncogenic agents or toxins be produced by this work? ☐ yes ☐ no

If yes, describe, what measures will be taken to minimize the risks of exposure and what steps will be taken to inactivate the hazards?

E4. Are virus or viral based promoters used in this work? ☐ yes ☐ no

If yes, list the promoter(s):

Amount of the viral genomic material: ☐ whole virus ☐ <2/3 ☐ <1/2

How is the virus used:

Can the virus infect human cells? ☐ yes ☐ no

If you are using a mammalian expression system, please provide a description of this system:

What is the host range of the virus?

Is the virus attenuated? ☐ yes ☐ no

Is there a potential to produce aerosols? ☐ yes ☐ no

If yes, how will you minimize?

Can the sequences recombine with endogenous or exogenous virus(es) to produce new and/or unpredictable forms of infectious virus?

☐ yes ☐ no If yes, explain:

Will the genetically modified virus encode for a factor associated with a disease? ☐ yes ☐ no

Do any of the sequences encode for any select agent toxins? ☐ yes ☐ no
https://www.selectagents.gov/sat/list.htm

I attest that the information contained in this application is accurate and complete. ***Initial*** ☐

I accept the responsibility for the safe conduct of all work with this study including all aspects of biosafety, chemical safety and physical hazards associated with my research. ***Initial*** ☐

I will formally notify all personnel, who may be at risk of potential exposure to these materials, of the appropriate procedures to conduct the research. ***Initial*** ☐

I agree to comply with the NIH requirements pertaining to the handling and shipment and transfer of recombinant DNA materials. I acknowledge my responsibility for the conduct of this research in accordance with the NIH guidelines. ***Initial*** ☐

I will not carry out the work described in that attached application until it has been approved by the Institutional Biosafety review committee and all requirements have been met.

Principal Investigator signature and date